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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KETTER, JAMES S

ART UNIT PAPER NUMBER

1636

DATE MAILED: 01/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,669

Applicant(s)

VAN ASBECK ET AL.

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-13 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of Group I, claims 7-19, in Paper No. 9, filed 12 November 2002, is acknowledged. The traversal is on the ground(s) that, in Applicants' view, PCT Rule 13 requires that a product and a method of its use must be examined together, and that the knowledge in the art of the alleged special technical feature does not permit restriction. Applicants also argue that no burden of search would be present. This is not found persuasive because, with respect to the presence of a putative special technical feature, it is submitted that the technical feature in common to the inventions does not meet the definition of a special technical feature:

37 CFR 1.475. Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

- (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention "). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features " shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Thus, it is apparent that the putative special technical feature must define a contribution that each invention makes over the prior art. The knowledge of bleomycin and adriamycin in the prior art, as noted in the rejections below, shows that the technical feature in question is not a special one.

With respect to the question of burden of search, it should be noted that the other limitations of the non-elected product claims would require a search different from that for the elected methods, and furthermore, the limitations of treatment for virions would not be present in the search for the non-elected products. Thus, the searches would not be co-extensive.

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The requirement is still deemed proper and is therefore made FINAL.

Claims 11-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

The disclosure is objected to because of the following informalities:

Pages 1 and 2 contain underlineations (underlines) of portions of the text, said underlineations apparently written by hand. These underlineations should be removed by amendment.

Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

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122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Smallheer (A, newly cited).

The instant claims are drawn, in part, to a method of treating a disease caused by a virion, most narrowly recited as HIV, comprising administration of a nucleic acid-binding chemotherapeutic agent, narrowly claimed as adriamycin.

Smallheer teaches, e.g., at column 1, lines 14-23, that treatment of viral disease, particularly AIDS (i.e., HIV infection) was known in the art to employ administration of adriamycin.

Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergamini et al. (U, newly cited).

The instant claims are drawn, in part, to a method of treating a disease caused by a virion, most narrowly recited as HIV, comprising administration of a nucleic acid-binding chemotherapeutic agent, narrowly claimed as adriamycin.

Bergamini et al. teaches, e.g., at the Abstract and the paragraph bridging pages 1239 and 1240, that treatment of HIV infection was known in the art to employ administration of adriamycin.

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Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Levine et al. (V, newly cited).

The instant claims are drawn, in part, to a method of treating a disease caused by a virion, most narrowly recited as HIV, comprising administration of a nucleic acid-binding chemotherapeutic agent, narrowly claimed as bleomycin.

Levine et al. teaches, e.g., at page 517, in the paragraphs labeled "BACKGROUND" through "CONCLUSIONS", the treatment of HIV-related lymphoma by administration of bleomycin.

Claims 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Cheng et al. (B, newly cited).

The instant claims are drawn, in part, to a method of treating a disease caused by a virion, comprising administration of a nucleic acid-binding chemotherapeutic agent, narrowly claimed as bleomycin.

Cheng et al. teaches, e.g., at column 1, lines 34-40, the treatment of HPV infection, i.e., condyloma acuminata, by administration of bleomycin.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of using a nucleic-acid binding compound which complexes a metal ion to treat a disease caused by a virion, wherein the compound-metal complex forms hydroxyl radicals from hydrogen peroxide. However, this represents a potentially very large genus, drawn together by recited functional properties, but not by any structural features except for the presence of a complexed metal ion. The potential number of species within this genus is very large, as no limitation on any structure or part of the structure is set forth. The number of potential molecular structures to bind metal ions is alone very large and varied. As such, the chemotherapeutic compounds recited in the specification do not constitute a representative sample of the genus of all recited compounds. Furthermore, the instant claims also include derivatives of bleomycin and adriamycin. However, the number of ways in which such compounds could be derivatized, i.e., altered in structure, is very large and varied. The written description of the claimed invention thus would not have conveyed to one of skill in the art at the time of filing, that Applicants had possession of the full scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 7-10, claim 7 recites “administering” the chemotherapeutic compound. However, there is no recitation of to whom or what such administration occurs.

With respect to claims 8-10, claim 8 recites “bleomycin, adriamycin and their derivatives.” However, such language might be understood as encompassing a compound derived from both bleomycin and adriamycin.

With further respect to claims 8-10, the term “derivatives” in claim 8 is unclear. A “derivative” has no precise definition in the art, but could have been understood to mean a second compound obtained from a first compound by an unspecified set of alterations to the structure of said first compound. This would thus encompass any compound conceivable. However, it would not appear that such was intended by Applicants. As presently drafted, the claims are thus of indeterminate metes and bounds.

Certain papers related to this application may be submitted directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to

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the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
January 23, 2003



**JAMES KETTER
PRIMARY EXAMINER**